Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Samuel Der-Yeghiayan	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	04 C 1876	DATE	8/18/2004
CASE TITLE	Jack Lawrence vs. Biotronik, Inc.		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ Local Rule 41.1 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] For the reason stated in the attached memorandum opinion order, the plaintiff's motion to remand is granted. All pending dates and motions are hereby denied as moot. Case ordered remanded back to the Circuit Court of Cook County. Terminating case.

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		number of notices
	No notices required.		AUG 19 2004
	Notices mailed by judge's staff.		date docketed
	Notified counsel by telephone.		
✓	Docketing to mail notices.		docketing deputy initials
	Mail AO 450 form.		
	Copy to judge/magistrate judge.		date mailed notice
MW	courtroom deputy's initials	Date/time received in central Clerk's Office	mailing deputy initials

Document Number

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JACK LAWRENCE, as Special Administrator of the Estate of JOHNNIE LAWRENCE, Deceased,	)	
Plaintiff,	)	
v.	)	**No. 04 C 1876**
BIOTRONIK, INC.,	)	
Defendant,	)	
and	)	
UNIVERSITY OF CHICAGO HOSPITALS,	)	
Respondent in Recovery.	)	

MEMORANDUM OPINION

SAMUEL DER-YEGHIAYAN, District Judge

This matter is before the court on Plaintiff Jack Lawrence's ("Lawrence"), motion to remand. For the reasons set forth below, we grant Lawrence's motion to remand.

BACKGROUND

Defendant Biotronik ("Biotronik") designs and distributes implantable cardiac

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pacemakers. Around June 27, 2001, Johnnie Lawrence at the age of 69 was implanted with a cardiac pacemaker distributed by Biotronik, Number 89963930. On February 13, 2002, Johnnie Lawrence died. Plaintiff Jack Lawrence, as special administrator of the estate of Johnnie Lawrence, brought the present suit against Biotronik in the Circuit Court of Cook County on February 4, 2004. Biotronik claims that the pacemakers it distributes have undergone a pre-market approval ("PMA") from the Food & Drug Administration ("FDA").

Congress enacted the Medical Devices Amendments of 1976("MDA") to provide for the safety and effectiveness of medical devices. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996). The MDA classifies such medical devices in three classes based on the level of risk each device poses to the public. *Id.* at 476. Pacemakers are Class III devices. *Id.* at 477. Class III consists of those devices that pose the highest risk of injury to human life. 21 U.S.C. § 360c(a)(1)(c). Before the FDA allows a Class III device to enter the market, the manufacturer must obtain a PMA to assure the safety and effectiveness of the device. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 905 (7th Cir. 1997). Under the PMA process, manufacturers must submit to the FDA "samples of the device, an outline of the device's components and properties, a description of the manufacturing process, copies of the proposed labels, various other data and information, and any other information the FDA requests." *Id.* (citing 21 C.F.R. § 814.20).

Lawrence filed this seven-count suit against Biotronik and the University of

Chicago Hospitals contending that the pacemaker Biotronik distributed to Johnnie Lawrence was improperly constructed and designed, and therefore was a direct and proximate cause of her death. The first six counts are against Biotronik, alleging strict liability for wrongful death (Count I), negligence for wrongful death (Count II), res ipsa for wrongful death (Count III), strict liability for a survival action (Count IV), negligence for personal injury (Count V), and res ipsa for personal injury (Count VI). The last count against the University of Chicago Hospitals alleges respondent in discovery, as Johnnie Lawrence was seen at the University of Chicago Hospitals in connection with her cardiology care (Count VII).

On March 11, 2004, Biotronik removed this case to the Northern District of Illinois pursuant to 28 U.S.C. § 1331. In its notice of removal, Biotronik asserted that federal question jurisdiction was proper on the grounds that the MDA preempts Lawrence's state law claims.

On March 15, 2004, Biotronik subsequently filed a motion for judgment on the pleadings. On April 1, 2004, Lawrence filed a motion to remand. Thus, the issues before the Court are initially whether we should remand this case to state court, and, if not remanded, whether to grant Biotronik's motion for judgment on the pleadings.

LEGAL STANDARDS

A party may file a motion to remand a case for improper removal based on

lack of subject matter jurisdiction pursuant to 28 U.S.C. § 1447(c). The party seeking removal bears the burden of establishing federal jurisdiction.*Doe v. Allied-Signal, Inc.*, 985 F.2d 908, 911 (7th Cir. 1993). Any doubt regarding jurisdiction should be resolved in favor of remanding to the state.*Id.* Furthermore, removal is only proper where the state-court claims could have originally been brought in federal court. 28 U.S.C. § 1441; *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987).

DISCUSSION

Lawrence has filed a motion to remand this action to state court. Biotronik removed this case pursuant to 28 U.S.C. § 1331, federal question jurisdiction, claiming that the MDA of the FDA preempts Lawrence's state law claims. Federal courts have federal question subject matter jurisdiction for cases that arise "under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. A claim arises "under the laws of the United States if the plaintiff's complaint raises a federal issue." *Lister v. Stark*, 890 F.2d 941, 943 (7th Cir. 1989).

Lawrence argues that Biotronik cannot remove this action to federal court based solely on federal preemption. Generally, "[f]ederal pre-emption is ordinarily a federal defense to the plaintiff's suit . . . [,] does not appear on the face of a well-pleaded complaint, and, therefore, does not authorize removal to federal court." *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 63 (1987). Biotronik argues that

this case can be removed based on the doctrine of complete preemption.

A removal may be warranted under the doctrine of complete preemption, which is an "'independent corollary' to the well-pleaded complaint rule." *Caterpillar Inc.*, 482 U.S. at 393. The complete preemption doctrine allows removal only where Congress has so completely preempted a particular area that no room remains for any state regulation and the complaint would be 'necessarily federal in character.' " *Bastien v. AT&T Wireless Services, Inc.*, 205 F.3d 983, 986-87 (7th Cir. 2000); *See also Rogers v. Tyson Foods, Inc.*, 308 F.3d 785, 788 (7th Cir. 2002)(stating that there is complete preemption if there is a "congressional intent in the enactment of a federal statute not just to provide a federal defense to a state created cause of action but to grant a defendant the ability to remove the adjudication of the cause of action to a federal court by transforming the state cause of action into a federal cause of action").

Biotronik claims that the complete preemption doctrine applies in the instant action. (Ans. Mot. Remand. 5). Biotronik claims that Congress intended to broadly preempt state law claims brought by injured plaintiffs against the manufacturers of medical devices. Biotronik cites several cases in support of its assertion that the complete preemption doctrine is applicable in the instant case. Biotronik cites *Bastien v. AT&T Wireless Services, Inc.*, 205 F.3d 983 (7th Cir. 2000). However, the holding in *Bastien* is only relevant to the extent that it offers the general rule of law regarding the complete preemption doctrine. In that case the court was dealing with consumer fraud claims involving cellular telephone services. *Id* at 985. Biotronik

also cites *Slater v. Optical Radiation Corporation*, 961 F.2d 1330, 1334 (7th Cir. 1992) in which the court addressed a case involving the manufacturing of lenses. However, in *Slater* the court did not address the PMA analysis or the doctrine of complete preemption. Biotronik also cites *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) to demonstrate preemption of state law claims. However, the issue in *Buckman Co.*, regarding whether claims alleging fraudulent representations to the FDA could be preempted, is inapplicable to the present case. *Id.* at 343.

Finally, Biotronik cites *Carby v. Irslinger*, 1996 WL 147916, at *2 (N.D. Ill. 1996). In *Carby* the court held that the "Plaintiff's products liability claim against the Defendant . . . is completely preempted by the FDA's pre-market approval process for all Class III medical devices." *Id.* at *2. However, the court in *Carby* merely stated in a conclusory fashion that the doctrine of complete preemption was applicable. *Id.* The court did not offer any analysis regarding why the doctrine of complete preemption applied.

Biotronik fails to offer any analysis explaining its contention that Congress intended to completely preempt the area of claims involving personal injury claims against the manufacturers of medical devices. Biotronik simply relies upon the above mentioned cases and states in a conclusory fashion that there is complete preemption. However, as the movant, Biotronik must do more than offer possible basis for removal and hope that the court will do its own independent research and support Biotronik's speculative conclusions. The United States Supreme Court

stated explicitly when commenting on the decision in *Metropolitan Life Insurance Co.* that complete preemption is not the norm, but rather occurs when "the pre-emptive force of a statute is . . .'extraordinary. . . .'" *Caterpillar Inc.*, 482 U.S. at 393.

The fact that the courts have found preemption in regards to devices approved under the less rigorous 510(k) process, *Metropolitan Life Ins. Co.*, 481 U.S. at 67, and have found that there is no preemption in regards to devices approved under the PMA process. *Mitchell*, 126 F.3d at 911, is an indication that congress did not intend to broadly preempt all state law claims in this area. The court in *Metropolitan Life Ins. Co.* specifically cautioned against a conclusion that Congress intended to completely preempt the area in question. 481 U.S. at 63-66. *See Comeau v. Heller*, 945 F.Supp. 7, at *11 (D. Mass. 1996)(holding that based on *Metropolitan Life Ins. Co.*, the complete preemption doctrine does not apply to claims by injured plaintiffs regarding the manufacture of medical devices). In addition, the court in *Mitchell* did not indicate it was addressing the issue of whether the defendant had a basis for removal under the complete preemption doctrine. In *Metropolitan Life Ins. Co.* and *Mitchell* the courts were reviewing a district court's decision to grant the defendant's motion for summary judgment. 481 U.S. at 61; 126 F.3d at 904.

There is some case law that suggests that the United States Supreme Court introduced an alternative analysis in *Metropolitan Life Ins. Co.* for the complete preemption doctrine. The approach has been referred to by the Northern District as the "replacement model." *McQuerry v. American Medical Systems, Inc.*, 899

F.Supp. 366, 369 (N.D. Ill. 1995)(delineating approaches into complete preemption model and replacement model). *See also Rogers*, 308 F.3d at 788(indicating that replacement model is an approach under complete preemption doctrine). *But see Bastien*, 205 F.3d at 986(indicating that the applicable standard for the complete preemption doctrine is whether Congress intended to completely preempt an area and not leave room for state claims); *Franczyk v. Cingular Wireless, LLC*, 2004 WL 178395, at *1 (N.D. Ill. 2004)(stating that "[i]n some instances, Congress has completely preempted a particular area where there is no room for any state regulation and the complaint is 'necessarily federal in character.'")

We shall briefly address the replacement model although Biotronik has argued exclusively under the approach set forth in *Bastien*. Under the replacement model "removal is appropriate only if federal law not only preempts the state claim but also replaces it with a federal remedy." *McQuerry*, 899 F.Supp. at 369. According to this line of cases, the "ability to bring suit under [federal law] is an element of 'complete preemption.'". *Rogers*, 308 F.3d at 788. The doctrine of complete preemption is not applicable "if a federal remedy did not exist in the alternative . . . [because] [o]therwise, a plaintiff would be forced into federal court with no relief available for 'vindicating the same interest.'" *Id.* Federal preemption trumps state law, "but the foundation for removal is the creation of federal law to replace state law." *Id.* Thus, "'unless the federal law has created a federal remedy--no matter how limited--the federal law, of necessity, will only arise as a defense to a state law action' and will thus not give rise to federal question jurisdiction underlying

complete preemption." *Id.*

The result in the instant case is the same under the replacement model. A federal private right of action must exist for the complete preemption doctrine. *Rogers*, 308 F.3d at 790. Biotronik has not shown that a private right of action exists in regards to the instant case and thus fails to show that the doctrine of complete preemption applies. Neither has Biotronik shown that any of the other requirements under the replacement model are met in the instant action.

Thus, Biotronik has failed to show that there was a valid basis for removal in the instant action and has failed to show that the complete preemption doctrine is applicable in the instant action. Therefore, since Biotronik has not shown a valid basis for removal, we grant Lawrence's motion to remand. *See Rogers*, 308 F.3d at 790(finding complete preemption absent when the defendant was unable to point out a private right of action); *McQuerry*, 899 F.Supp. at 371(holding that "the MDA is not a statute that preempts state law so completely as to render state claims federal in nature."); *Goldstein v. W.L. Gore & Associates, Inc*, 887 F.Supp. 168, 171 (N.D. Ill. 1995)(holding that defendant "failed to identify any legislative history that demonstrates a Congressional intent to confer upon the Medical Device Amendments or the FDCA the same extraordinary pre-emptive power as that of LMRA and ERISA " and that "[t]o the contrary, the Seventh Circuit has emphasized that the scope of preemption under the Medical Device Amendments is more narrow than that of other federal statutes like ERISA.").

CONCLUSION

Based on the foregoing analysis, we grant Lawrence's motion to remand. All pending motions are denied as moot.

Samuel Der-Yeghiayan
United States District Court Judge

Dated: August 18, 2004